

Appl. No. 10/078,042
Docket No. 8430
Amdt. dated February 5, 2008
Reply to Office Action mailed on September 10, 2007
Customer No. 27752

REMARKS

Claim Status

Claims 1 – 10 are pending in the present application. No additional claims fee is believed to be due.

Claims 1 and 9 have been amended to include the feature of statistical control chart techniques based on the historical or recent health data of the individual. Support for this amendment is found at page 15, lines 14-30 and figures 3, 4, and 6 of the specification.

Claim 1 has been amended to include the feature of the data acquisition mechanism and the data measurement mechanism being disposed on a single handheld device. Support for this amendment is found at page 13, lines 7-10

Claim 6 has been amended to include the feature of the displayed information comprising a statistical control chart based on the historical or recent health data of the individual. Support for this amendment is found at page 15, lines 14-30 and figures 3, 4, and 6 of the specification.

Claim 8 has been amended to include the feature of a target. Support for this amendment is found at page 18, lines 6-7 of the specification.

New claims 14-15 have been added. Support for this amendment is found at page 16, lines 20-24 of the specification.

New Claims 16-20 have been added. Support for this amendment is found at page 17, lines 12-25 of the specification.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §103(a) Over Sheehan in View of Frasca Jr.

Claims 1-2, 5-7 and 9-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,319,199 to Sheehan, *et al.*, (hereinafter "Sheehan") in view of U.S. Pat. No. 6,055,506 to Frasca Jr., *et al.*, (hereinafter "Frasca"). Applicants respectfully traverse the rejection.

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To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (MPEP §2143).

With regard to claim 1, the Office Action states that Sheehan does not teach "at least one data analysis mechanism generating information pertaining to the health of an individual wherein the data analysis mechanism performs at least analysis selected from the group of population comparison, multi-variate analysis, attribute data analysis, and reliability engineering analysis." (The Office Action, bottom of page 2-top of page 3). The Office Action looks to Frasca for the missing disclosure. As best understood by Applicants, the Office Action is citing the clinical range disclosed in Frasca for the teaching of a population comparison. (The Office Action, page 3).

With regard to the population comparison, the Office Action states "the Frasca Jr. reference does in fact teach a population comparison (Col. 3, Ln. 21-26) since a patient's data is compared with a predetermined limit . . . [which] must inherently be derived from a population of more than one individual based on past experience . . . **Frasca, Jr. does not state that the predetermined limit is generated based on the outpatient's own data.**" (The Office page 8, bottom-page 9, top).

Claims 1 and 9 recite, *inter alia*, a data analysis mechanism that performs at least one analysis selected from the group of: statistical control chart techniques based on the historical or recent health data of the individual, multi-variate analysis, attribute data analysis, and reliability engineering analysis. Applicants would like to point out that claims 1 and 9 no longer recite a population comparison. Further, Applicants are unable to find any teaching or suggestion in Sheehan or Frasca of a data analysis mechanism performing statistical control chart techniques based on the historical or recent health data of the individual, as recited in claims 1 and 9 of the present application.

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Claim 1 also recites, *inter alia*, a data acquisition mechanism and a data measurement mechanism both disposed on a single handheld device. As best understood by Applicants, the Office Action is citing col. 8, lines 18-32 of Sheehan to support an assertion that the base unit 300 of Sheehan is a data acquisition device. (See the Office Action page 3, bottom and page 4, middle). Applicants submit that the base unit 300 of Sheehan and the otoscope of Sheehan are clearly disclosed as two separate devices. (Sheehan, figure 8 and col. 7, lines 53-67)

Claim 6 recites, *inter alia*, information being displayed as a statistical control chart based on the historical or recent health data of the individual. For the sake of brevity, Applicants will not repeat the above remarks with regard to claims 1 and 9. It is Applicants' position that the combination of Sheehan and Frasca does not teach or suggest displayed information comprising a statistical control chart based on the historical or recent health data of the individual, as is recited in claim 6 of the present application.

With regard to claim 7, Applicants continue to take the position that the combination of Sheehan and Frasca does not teach or suggest a data acquisition mechanism comprising a PDA or a handheld computer. As best understood by Applicants, the Office Action looks to Sheehan, Figures 3-5 and col. 8, lines 18-32 to support the position that the Sheehan discloses a PDA or handheld computer. Applicants appreciate that the otoscope of Sheehan may be handheld, however, it is Applicants position that, absent some evidence to the contrary, one of ordinary skill in the art would not recognize the otoscope to be a PDA or handheld computer.

The Office Action states "[a]s per claim 9, Sheehan in view of Frasca, Jr. teach . . . measuring the at least one health parameter of interest and pertinent environmental or qualitative information to produce data (Sheehan: col. 2, Ln. 23-46)." (The Office Action, page 4). Looking to the cited portion of Sheehan, Applicants are unable to find any disclosure of measuring environmental or qualitative information. The present application discloses that qualitative observations are attributes and may include qualitative ratings or remedies for a health event. (The present application, page 9, lines 23-30). The present application discloses that environmental influences may include pollen or mold count, barometric pressure changes, weather conditions, and exposure to pets or smokers. (The present application, page 10, lines 6-17). The cited portion of Sheehan mentions the word environment, but as best understood by

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applicants it is referring to a particular venue in which the system 100 of Sheehan may be deployed in. (Sheehan, col. 2, lines 24-27). Thus, it is Applicants' position that the cited portion of Sheehan does not teach or suggest measuring environmental or qualitative data.

The Office Action states, Sheehan does not teach "analyzing the data . . . to define at least one of an out-of-control situation requiring intervention and/or potential causes or remedies of an out-of-control situation wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison" (The Office Action page 4, bottom-page 5, top). The Office looks to Frasca for the missing disclosure.

As pointed out above, claim 9 no longer recites a population comparison. In addition, it is Applicants position that Frasca does not teach or suggest analyzing data to define an out-of-control situation, as recited in claim 9 of the present application. An out-of-control situation is disclosed as a situation where a health parameter of interest for a particular individual violates a control rule. (See, page 17, lines 8-30 of the present specification). Applicants submit that one of ordinary skill in the statistical process control art would recognize that out-of-control limits are based on statistical control rules and are intended to indicate a statistically significant change in a parameter of interest for an individual, as opposed to normal variation within the statistically likely boundaries for the individual. Applicants are unable to find any disclosure in Frasca of a measured parameter violating a control rule. Thus, it is Applicants position that Frasca, alone or combination with Sheehan, does not teach or suggest an out-of-control situation or potential cause or remedy of an out-of-control situation, as recited in claim 9 of the present application.

In light of the above remarks it is Applicants' position that the combination of Sheehan and Frasca does not teach or suggest each and every element recited in claims 1, 6, or 9 or any claim depending therefrom. Accordingly, Applicants respectfully request that the rejection of claims 1-7 and 9-10 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

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**Rejection Under 35 USC §103(a) Over Sheehan in View of Frasca and Falcone and
Zadrozny**

Claim 8 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan, in view of Frasca and further in view of U.S. Pat. No. 5,464,102 to Falcone (hereinafter "Falcone") and U.S. Pat. No. 6,540,674 to Zadrozny, *et al.* (hereinafter "Zadrozny"). Applicants respectfully traverse the rejection.

With regard to claim 8, the Office Action looks to Frasca for the disclosure of a population comparison. (The Office Action, page 6). For the sake of brevity, Applicants will not repeat the remarks made above with regard to a population comparison and the lack of teaching or suggestion in Sheehan and Frasca of a control limit. Applicants submit that Falcone and Zadrozny do not overcome this lack of teaching or suggestion.

The Office Action further states with regard to claim 8, "Sheehan in view of Frasca, Jr. do not teach that the data acquisition mechanism is adapted to perform a preliminary analysis on the data and provide an output (e.g., an alarm) when the data comprises a value that is outside of a control limit, however, this feature is taught by Falcone (Col. 2, Ln. 9-18 and Col. 4; Ln. 22-25)." (The Office Action, page 6). Applicants respectfully disagree.

First, it is Applicants' understanding that Falcone does not teach or suggest a control limit, as recited in claim 8 of the present application. Falcone discloses the use of target limits and dynamic limits. (See Falcone, Col. 3, lines 57-65; Col. 4, lines 1-29). As best understood by Applicants, the dynamic limits are merely target limits that are modified according to an expected reaction of a patient's health parameter in response to a procedure and which are programmed to return to the original target limits over time. (Falcone, col. 4, lines 1-10). Thus, it is Applicants' position that the target limits of Falcone are not the same as the control limits recited in claim 8 of the present application.

Second, Applicants are unable to find any teaching or suggestion of a preliminary analysis in Falcone. As best understood by Applicants, physiological parameter measurements obtained by the sensors are supplied to a system processor that process the data and sends it to a display controller to be displayed. Applicants submit that the physiological parameter

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measurement data of Falcone is analyzed only once. Thus, it is Applicants' position that Falcone does not teach or suggest a data acquisition mechanism adapted to perform a preliminary analysis mechanism on data and provide an output when the data comprises a value that is outside of a target.

In addition, Applicants respectfully submit that Falcone teaches away from Sheehan, Frasca, and Zadrozny and is therefore unavailable to properly support an obviousness rejection. As best understood by Applicants, Sheehan, Frasca, and Zadrozny are clearly directed to devices for use outside of a medical institution such as a hospital. (See Sheehan and Frasca, titles and abstracts). Falcone, on the other hand, discloses a bedside patient monitoring system. (Falcone, col. 2, lines, 60-62). Falcone discloses "[p]atient monitoring systems are commonly used for monitoring the condition of a patient, such as in coronary care units and intensive care units of a hospital." (Falcone, col. 1, lines 14-16).

Case law clearly indicates that it is improper to combine references where the references teach away from their combination. (*In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). In this case, the devices of Sheehan, Frasca, and Zadrozny are directed for use away from a medical institution, while the device of Falcone is directed for use in a medical institution. Therefore, it is Applicants' position that the disclosure of Falcone amounts to a teaching away from Sheehan, Frasca, and Zadrozny.

The Office Action looks to Zadrozny for the disclosure of information including at least on level of intervention when the data comprises a value that is outside of a control limit. (The Office Action, page 6, bottom-page 7, top). Applicants are unable to find any teaching or suggestion of a control limit in Zadrozny.

It is Applicants' position that the combination of Sheehan, Frasca, Zadrozny and Falcone is improper and that even if it were proper, the combination still does not teach or suggest each and every element recited in claim 8 of the present application. Accordingly, Applicants respectfully request that the rejection of claim 8 under 35 U.S.C. 103(a) be reconsidered and withdrawn.

App'l. No. 10078/442
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Rejection Under 35 U.S.C. §103(a) Over Sheridan in view of Fraica and Ekblad

Claim 3 has been rejected under 35 U.S.C. 103(a) over Sheridan in view of Fraica and U.S. Pat. No. 5,920,478 to Ekblad, et al. (hereinafter "Ekblad"). Applicants respectfully traverse the rejection.

Even assuming, arguendo, that Ekblad contains the disclosure for which it is cited, Ekblad still does not overcome the lack of teaching or suggestion mentioned above with regard to claim 1, from which claim 3 depends. Accordingly, Applicants respectfully request that rejection of claim 3 under 35 U.S.C. 103(a) over Sheridan in view of Fraica and Ekblad be reconsidered and withdrawn.

Rejection Under 35 U.S.C. §103(a) Over Sheridan in view of Fraica and Lerman

Claim 4 has been rejected under 35 U.S.C. 103(a) over Sheridan in view of Fraica and U.S. Pat. No. 5,642,582 issued to Lerman, et al. (hereinafter "Lerman"). Applicants respectfully traverse the rejection.

Even assuming, arguendo, that Lerman contains the disclosure for which it is cited, Lerman does not overcome the lack of teaching or suggestion of Sheridan and Fraica described above with regard to claim 1, from which claim 4 depends. Accordingly, Applicants respectfully request that the rejection of claim 4 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied reference(s). In view of the foregoing, entry of the amendment(s) presented herein, reconsideration of this application, and allowance of the pending claim(s) are respectfully requested.

Respectfully submitted,

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Date: February 5, 2008
Customer No. 27752